

REMARKS

I. Amendments to the Claims

Claim 6 has been amended to recite ethanol of “about 10%.” Support for this amendment is found in the Specification at page 21, lines 19-26.

Claims 46 and 47 have accordingly been cancelled.

No new matter has been added.

II. Claim Rejections

The Examiner rejects claims 6, 14, 18, and 41-47 under 35 U.S.C. § 103 as unpatentable over Azuma in view of Van Nest. Applicants respectfully traverse.

The Examiner has misconstrued the disclosure of Van Nest because Van Nest teaches adding an emulsifying agent to a composition consisting of an oil and a muramyl dipeptide derivative, to obtain an oil droplet having the particle size of less than one micron. But muramyl peptide is a small molecule that has a peptidoglycan constituent, which is extracted.

(Specification page 3, lines 13-22.) In contrast, BCG-CWS is a poorly-soluble, complex macromolecule. (Specification, page 3, lines 7-12 and Declaration of November 7, 2008.) Van Nest discloses only muramyl peptide derivatives as immunostimulating agents and is silent about adjusting the particle size in the oil droplet in the emulsion comprising BCG-CWS.

Moreover, Van Nest teaches that the particle size in the oil droplet (and consequently the oil droplet size) will vary with the immunostimulating agent (Van Nest, page 8, lines 25-26). However, Van Nest does not teach how one of skill would reduce the particle size in the oil droplets where, like BCG-CWS, the particles are large and poorly soluble in either water or organic solvents.

Additionally, in the present invention, the BCG-CWS and squalane are dispersed in the specific organic solvent and then the organic solvent is removed by distillation. The organic solvent is therefore not contained in the claimed “paste” and cannot be equivalent to the

“emulsifying agent” of Van Nest. Thus, Applicants submit that the prior art disclosure does not teach every element of the claims.

As for the combination of Van Nest and Azuma, one of skill would not find the present invention obvious because Azuma, like Van Nest, does not teach how one of skill would reduce the particle size to the claimed range. Namely, Azuma does not even suggest the paste obtained by their procedure would have the specific particle size distribution and improved stability of the claimed invention. Accordingly, Applicants request that the rejection be withdrawn.

In summary, neither Van Nest nor Azuma disclose how to address the problem of obtaining a dispersion of an insoluble or poorly soluble material such as BSC-CWS having an acceptable particle size distribution according to the invention. Therefore the references, alone or combined, do not enable the present invention and furthermore do not establish any expectation of success in making the claimed invention. The references especially fail to suggest how to obtain a paste that provides a stable emulsion of BSC-CWS when combined with an aqueous phase. Accordingly, the instant rejection should be withdrawn.

Furthermore, though the Examiner asserts that the characteristics of the BCG-CWS paste in Azuma are made by “*nearly identical*” methods, the Examiner has no basis for concluding that the viscosity characteristics of the paste of Azuma would be inherently identical. Inherency requires that the characteristic be “necessarily” present. The fact that a certain result or characteristic *may* occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 28 USPQ2d 1955 (Fed. Cir. 1993). To establish inherency, the extrinsic evidence “must make clear that the missing descriptive matter is necessarily present”. *In re Robertson*, 169 F.3d 743, 49 USPQ2d 1949 (Fed. Cir. 1999). The mere fact that a certain thing might result from a given set of circumstances, or is even probable, is not sufficient. *Id.* Thus, because the method of making the two pastes is NOT identical, and as discussed above, the method of making the particles affects their size and the viscosity of the paste, Applicants submit that the Examiner’s assertions of inherency fail as a matter of law. Accordingly, Applicants request that the Examiner withdraw the rejection.

Finally, the Examiner has declined to accept the evidence of the Declaration of Dr. Nomura made of record Nov. 7, 2008. The Examiner takes a position that the scope of the claims is broader than the showing in the Declaration. The claims now recite the proportions of heptane and ethanol described in the experiments of the Nomura Declaration, and so the showing in the Declaration is indeed commensurate in scope with the present claims.

Thus, the evidence of unobviousness provided by the Nomura Declaration should now be considered favorably by the Examiner and such is respectfully requested.

Applicants submit that the present claims are allowable. The favorable actions of withdrawal of the standing rejections and allowance of the claims are requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell Reg. No. 36,623 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

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Respectfully submitted,

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